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K001403

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

INFINITY™ Glucose Reagent, Procedures 17/18

Sigma Diagnostics INFINITY™ Glucose Reagent is intended for the in vitro quantitative, diagnostic determination of glucose in human serum or urine on both automated and manual systems.

The accurate estimation of glucose is important in the diagnosis and management of hyperglycemia and hypoglycemia. Hyperglycemia may occur as a result of diabetes mellitus, in patients receiving glucose containing fluids intravenously, during severe stress and cerebrovascullar accidents. Hypoglycemia may be the result of an insulinoma, insulin administration, inborn errors of carbohydrate metabolism or fasting.[1] Often in the investigation of these disorders glucose determinations are performed in conjunction with various tolerance tests or simulation tests. For a more detailed discussion of glucose metabolism the user should refer to a standard textbook such as Kaplan.[2]

The hexokinase/glucose-6-phosphate dehydrogenase method developed by the American Association of Clinical Chemistry and Centers for Disease Control has been accepted as the reference method for glucose determination. In that procedure protein free filtrates prepared by the Somogyi technique using $ZnSO_4$ / $BaSO_4$ precipitation are used. For routine laboratory use however, serum or plasma without protein removal is the preferred method. The Sigma Diagnostics INFINITY Glucose Reagent is based on the reference method.

The series of reactions involved in the assay system is as follows:

1. Hexokinase (HK) catalyses the phosphorylation of glucose by adenosine-5'-triphosphate (ATP) producing adenosine-5'-diphosphate (ADP) and glucose-6-phosphate (G-6-P).

   $$\text{Glucose} + \text{ATP} \xrightarrow{\text{HK}} \text{G-6-P} + \text{ADP}$$

2. G-6-P is oxidized to 6-phosphogluconate (6-PG) with the reduction of nicotinamide adenine dinucleotide (NAD^+) to reduced NAD (NADH) by glucose-6-phosphate dehydrogenase (G-6-PDH). The amount of NADH formed is proportional to the concentration of glucose in the sample and can be measured by the increase in absorbance at 340 nm.

   $$\text{G-6-P} + NAD^+ \xrightarrow{\text{G-6-PDH}} \text{6-PG} + \text{NADH} + H^+$$

The Sigma Diagnostics INFINITY™ Glucose Reagents (Procedure No. 17/18) are substantially equivalent to, and are the same products as the TRACE Scientific Glucose Reagents cleared by the FDA as K980026.

Correlation studies to Sigma Diagnostics Glucose (HK) Reagent, Procedure No. 16 (K945908) using plasma and CSF samples yielded regression equations of:

Plasma	INFINITY Glucose = 0.993 (Glucose 16) + 0.04 (N=126)
CSF	INFINITY Glucose = 1.028 (Glucose 16) - 0.63 (N=18)

References

1. Zilva JF, Pannall PR: Carbohydrate Metabolism in "Clinical Chemistry in Diagnosis and Treatment". Lloyd-Luke, London 1979, Chap 9: 174-214
2. Clinical Chemistry Theory, Analysis and Correlation. Kaplan LA, Pesce AJ (Eds.), CV Mosby Company, St. Louis, MO. 1257-61, 1984

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 0 2000

William R. Gilbert, Ph.D.
Manager, Scientific Affairs
Sigma Diagnostics, Inc.
545 South Ewing Avenue
St. Louis, Missouri 63103

Re: K001403
Trade Name: Infinity Glucose Reagent
Regulatory Class: II
Product Code: CFR
Dated: July 21, 2000
Received: July 24, 2000

Dear Dr. Gilbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: INFINITY™ Glucose Reagent

Indications For Use:

The Sigma Diagnostics INFINITY™ Glucose Reagent is a device intended to measure glucose quantitatively in serum, plasma, CSF, or urine. Measurements obtained by the device are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001403

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use** ____
(Per 21 CFR 801.109)